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WilmerHale/Columbia University 399 PARK AVENUE NEW YORK, NY 10022			SOREY, ROBERT A	
		ART UNIT	PAPER NUMBER	
		3626		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/600,269	WANG ET AL.	
	Examiner	Art Unit	
	ROBERT SOREY	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 November 2008.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 17-42 is/are pending in the application.
 4a) Of the above claim(s) 1-16 and 43-50 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 17-42 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 20 June 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III in the reply filed on 12/11/2008 is acknowledged. The traversal is on the ground(s) that no serious burden would be imposed on the Examiner if the restriction were not required. This is not found persuasive because subcombination I has separate utility for all other subcombinations such as specifying auxiliary tasks embedded within primary tasks; subcombination II has separate utility from all other subcombinations such as arranging execution task classes, structure element classes, and execution constraint classes in hierarchies to form subontologies; subcombination III has separate utility from all other subcombinations such as integrating the generalized guideline execution tasks; and subcombination IV has separate utility from all other subcombinations such as presenting a user interface allowing the selection of project files. Additionally, each invention can be directed towards a separate and distinct subclass and to examine the claims in light of each subclass would require a different search thereby creating a serious and undue burden for the Office.

2. The requirement is still deemed proper and is therefore made FINAL.

Status of Claims

3. Claims 1-16 and 43-50 have been restricted. Claims 17-42 are presented for examination.

Claim Objections

4. **Claims 25 and 38** are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant presents “if” statements and the Examiner has considered the alternate situations in which nothing is performed by the claims. Because nothing is performed by the claims they fail to be further limiting.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. **Claims 17-29** are rejected under 35 U.S.C. 101 based on Supreme Court precedent and recent Federal Circuit decisions. The Office's guidance to examiners is that a § 101 process must (1) be tied to another statutory class (such as a particular machine) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. *In re Bilsky*, 88 U.S.P.Q.2d 1385 (Fed. Cir. 2008); *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); and *Cochrane v. Deener*, 94 U.S. 780,787-88 (1876).

7. An example of a method claim that would not qualify as a statutory process would be a claim that recited purely mental steps. Thus, to qualify as a § 101 statutory process, the claim should positively recite the other statutory class (the thing or product)

to which it is tied. This can be done, for example, by identifying the apparatus that accomplishes the method steps, by positively reciting the subject matter that is being transformed, or by identifying the material that is being changed to a different state.

8. Applicant's method steps in claims 17-29 fail the first prong of the new Federal Circuit decision since they are not tied to another statutory class and can be preformed without the use of a particular apparatus. Furthermore, the method steps fail to transform underlying subject matter to a different state or thing. For example, claim 17 teaches extracting generalized guidelines takes from a model and integrating the guidelines into a generic model, but in no way is it clear as to how this is accomplished (such as, accomplished by a particular **machine**). It is recommended that Applicant simply add any structural language from the specification as necessary to complete a statutorily compliant method having Applicant's desired capabilities.

9. As per **claims 30-42**, 35 USC 101 requires that in order to be patentable the invention must be a "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" (emphasis added). Applicant's claims mentioned above are intended to embrace or overlap two different statutory classes of invention as set forth in 35 USC 101. For example, claim 30 begins by discussing a system ("A system for providing..."), but then claims method steps ("performs a method comprising..."). "A claim of this type is precluded by the express language of 35 USC 101 which is drafted so as to set forth the statutory classes of invention in the alternative only", Ex parte Lyell (17 USPQ2d 1548). See also, 35 USC 112, second paragraph, rejections concerning claims 30-42 below. It is recommended

that Applicant simply remove the “method” recitation and add any structural language from the specification as necessary to complete a statutorily compliant system having Applicant's desired capabilities. NOTE: For purposes of applying art, the Examiner interprets the claims as best as possible in light of the 101 issues (and the corresponding 112 issues below).

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. **Claims 18, 21-26, and 30-42** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 18 is rejected for reciting “further comprising integrating representation elements not found in the guideline representation model into the generic representation model” because it is unclear where these representation elements come from. Claim 31 is rejected for similar reasons.

13. As per claims 21-26, they are claim dependent upon claim 20 which states that generalized guideline execution tasks comprise "at last one of: input elements, output elements, subtasks, and execution constraints". Claim 21 relies upon the "output elements"; claim 22 relies upon the "input elements"; claim 23 relies upon the "output elements"; claim 24 relies upon the "subtasks"; claim 25 relies upon the "subtasks"; and claim 26 relies upon the "execution constraints". However, if only “one of” the tasks listed in claim 20 is selected, the claims depending on the remaining elements are

indefinite because they rely to an unselected element in a claim from which they depend and it is unclear what is meant by the claims in such a situation. For this reason claims 21-26 are indefinite. Claims 34-39 are rejected for similar reasons.

14. Claim 21 is rejected again for reciting "the representation elements" because there is a lack of antecedent basis for the limitation "the representation elements" in the claims. Claim 33 is rejected for similar reasons.

15. Claim 24 is rejected again for reciting "current guideline execution tasks" because it is unclear as to what is meant by "current". Are the current tasks those which were extracted in the first limitation of claim 17? Claim 33 is rejected for similar reasons.

16. Claim 24 is rejected again for reciting "other tasks" because it is unclear as to what is meant by "other". There is a lack of antecedent basis for the "other tasks" in the claims. It is unclear as to what these "other tasks" are and where they came from. Claim 33 is rejected for similar reasons.

17. Claims 30-42 are rejected for not being sufficiently precise due to the combining of two separate statutory classes of invention in the independent claim and the dependent claims. The preamble of the independent claim refers to a system and method.

Nonfunctional Descriptive Material

18. As per **claims 20-28 and 33-41**, the Examiner has placed little weight on what the guideline execution tasks comprise of since the effect of different types of tasks on the method steps of extracting and integrating in claims 17 was not made clear in the claims and did not alter or change those steps. Therefore, what the guideline execution

tasks comprise of, including their types and relationships, is nonfunctional descriptive material and is not given weight for the purposes of examination. To specifically exemplify, this is especially true of claims 21 and 33, which describe what the input and output elements are derived from and do not contain a step or have effect on any step. The Examiner has cited portions of the prior art that read on the nonfunctional descriptive material in the claims where convenient. See: Ex parte Herman Mathias, Appeal No. 2005-1851, Application No. 09/612788; and Ex parte James Prescott Curry, Appeal No. 2005-0509, Application No. 09/449237.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. **Claims 17 and 30** are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,574,828 to Hayward.

21. As per claim 17, Hayward teaches a method for providing a generic guideline representation model for use by a guideline execution engine, the method comprising:

--extracting generalized guideline execution tasks from a guideline representation model having representation elements (see: Hayward, column 10, line 56 through column 11, line 15, is met by the Guideline Editor which accesses a library containing plurality of health care guideline sources (developers); and column 19, line 5 through

column 20, line 24, is met by the Guideline Editor being used to “retrieve” guidelines from developers for synthesis into the system); *and*

--integrating the generalized guideline execution tasks to form a generic guideline representation model (see: Hayward, column 10, line 56 through column 11, line 15, is met by the Guideline Editor synthesizing the accessed guidelines into the system; and column 19, line 5 through column 20, line 24, is met by the Guideline Editor retrieving guidelines from developers).

22. As per claim 30, Hayward teaches a system for providing a generic guideline representation model for use by a guideline execution engine, the system comprising at least one computing device including software that, when executed, performs a method comprising (see: Hayward, column 4, lines 47-65):

--extracting generalized guideline execution tasks from a guideline representation model having representation elements (see: Hayward, column 10, line 56 through column 11, line 15, is met by the Guideline Editor which accesses a library containing plurality of health care guideline sources (developers); and column 19, line 5 through column 20, line 24, is met by the Guideline Editor being used to “retrieve” guidelines from developers for synthesis into the system); *and*

--integrating the generalized guideline execution tasks to form a generic guideline representation model (see: Hayward, column 10, line 56 through column 11, line 15, is met by the Guideline Editor synthesizing the accessed guidelines into the system; and column 19, line 5 through column 20, line 24, is met by the Guideline Editor retrieving guidelines from developers).

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. **Claims 18, 20-28, 31, and 33-41** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,574,828 to Hayward in view of U.S. Patent 6,188,988 to Barry.

25. As per claim 18, Hayward teaches the invention substantially as claimed, see discussion of claim 17, but fails to specifically teach:

--further comprising integrating representation elements not found in the guideline representation model into the generic representation model.

However, Barry teaches an inference engine that includes a plurality of knowledge bases, including regimens (i.e., guidelines) and rules (i.e., guidelines), that can be utilized to generate customized regimens and corresponding advisory information (Fig. 2)(see: Barry, abstract, and column 10, line 23 through column 12, line 60).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hayward and Barry. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and

one of ordinary skill in the art would have recognized that the results of the combination were predictable.

26. As per claims 20, 21, and 22, Hayward teaches the invention substantially as claimed, see discussion of claim 17, but fails to specifically teach:

--wherein the generalized guideline execution tasks comprise at least one of: input elements, output elements, subtasks, and execution constraints.

--wherein the input elements and output elements are static structure elements derived from the representation elements.

--wherein the input elements define participants for a guideline execution task.

Note that the Examiner chooses to evaluation the guideline execution task of concerning "input elements".

However, Barry teaches input elements that are static structure elements derived from representation elements and define participants for a guideline execution task (see: Barry, abstract, and column 10, line 35 through column 12, line 60, especially column 11, lines 18-64, input static structure elements derived from representation elements is met by the "premise" elements such as "ddC" and conditional associations; for this example, the premise is for the inference engine to determine whether or not a therapy being evaluated (i.e., "eval therapy") contains the antiretroviral drug "ddC"; and especially, column 10, lines 51-57, input elements define participants is met by Rule #1 for an eval therapy).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hayward and Barry. The well known

elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

27. As per claim 23-27, these claims are directed towards an unselected species of claim 20. As indicated earlier, the Examiner has chosen the “input elements” to evaluate and has rejected the limitation thereby rendering the other limitations moot and further rendering claims dependent upon those unselected limitations moot as well.

Furthermore, as per claim 25, the Examiner considers the situation wherein the guideline execution task does not comprise of subtasks; therefore, the claim ceases to be further limiting.

28. As per claims 28, Hayward teaches the invention substantially as claimed, see discussion of claim 17, but fails to specifically teach:

--wherein the representation elements of the guideline representation model comprise structural specifications that define static structure elements and execution constraints.

However, Barry teaches representation elements that define static structure elements and execution constraints (see: Barry, abstract, and column 10, line 35 through column 12, line 60, is met by the rules and their associated conditional constraints, including boundary conditions (see: Barry, Table 3) and the rules that filter therapies).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hayward and Barry. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

29. As per claim 31, Hayward teaches the invention substantially as claimed, see discussion of claim 30, but fails to specifically teach:

--wherein the method further comprises integrating representation elements not found in the guideline representation model into the generic representation model.

However, Barry teaches an inference engine that includes a plurality of knowledge bases, including regimens (i.e., guidelines) and rules (i.e., guidelines), that can be utilized to generate customized regimens and corresponding advisory information (Fig. 2)(see: Barry, abstract, and column 10, line 23 through column 12, line 60).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hayward and Barry. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

30. As per claims 33, 34, and 35, Hayward teaches the invention substantially as claimed, see discussion of claim 30, but fails to specifically teach:

--wherein the generalized guideline execution tasks comprise at least one of: input elements, output elements, subtasks, and execution constraints.

--wherein the input elements and output elements are static structure elements derived from the representation elements.

--wherein the input elements define participants for a guideline execution task.

Note that the Examiner chooses to evaluation the guideline execution task of concerning "input elements".

However, Barry teaches input elements that are static structure elements derived from representation elements and define participants for a guideline execution task (see: Barry, abstract, and column 10, line 35 through column 12, line 60, especially column 11, lines 18-64, input static structure elements derived from representation elements is met by the "premise" elements such as "ddC" and conditional associations; for this example, the premise is for the inference engine to determine whether or not a therapy being evaluated (i.e., "eval therapy") contains the antiretroviral drug "ddC"; and especially, column 10, lines 51-57, input elements define participants is met by Rule #1 for an eval therapy).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hayward and Barry. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and

one of ordinary skill in the art would have recognized that the results of the combination were predictable.

31. As per claim 36-40, these claims are directed towards an unselected species of claim 33. As indicated earlier, the Examiner has chosen the “input elements” to evaluate and has rejected the limitation thereby rendering the other limitations moot and further rendering claims dependent upon those unselected limitations moot as well.

Furthermore, as per claim 38, the Examiner considers the situation wherein the guideline execution task does not comprise of subtasks; therefore, the claim ceases to be further limiting.

32. As per claims 41, Hayward teaches the invention substantially as claimed, see discussion of claim 30, but fails to specifically teach:

--wherein the representation elements of the guideline representation model comprise structural specifications that define static structure elements and execution constraints.

However, Barry teaches representation elements that define static structure elements and execution constraints (see: Barry, abstract, and column 10, line 35 through column 12, line 60, is met by the rules and their associated conditional constraints, including boundary conditions (see: Barry, Table 3) and rules that filter therapies).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hayward and Barry. The well known elements described are merely a combination of old elements, and in the combination,

each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

33. **Claims 19 and 32** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,574,828 to Hayward in view of U.S. Patent 7,366,711 to McKeown.

34. As per claim 19, Hayward teaches the invention substantially as claimed, see discussion of claim 17, but fails to specifically teach:

--wherein the generalized guideline execution tasks are common to at least two guideline representation models.

However, McKeown teaches extracting phrases that have common focus elements from a collection of related documents to form a coherent summary (see: McKeown, abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hayward and McKeown. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

35. As per claim 32, Hayward teaches the invention substantially as claimed, see discussion of claim 30, but fails to specifically teach:

--wherein the generalized guideline execution tasks are common to at least two guideline representation models.

However, McKeown teaches extracting phrases that have common focus elements from a collection of related documents to form a coherent summary (see: McKeown, abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hayward and McKeown. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

36. **Claims 29 and 42** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,574,828 to Hayward in view of U.S. Patent 6,188,988 to Barry further in view of U.S. Patent 7,366,711 to McKeown.

37. As per claim 29, Hayward teaches the invention substantially as claimed, see discussion of claim 28, but fails to specifically teach:

--further comprising mapping the static structure elements and the execution constraints to corresponding static structure elements and execution constraints of the generic guideline representation model, to provide a mapping relationship for use by a guideline execution engine.

However, McKeown teaches directly teaches mapping elements (see: McKeown, column 2, lines 37-41), and Barry also teaches rules that incorporate specific elements from knowledge bases into customized treatments and corresponding advisory information (Fig. 2)(see: Barry, column 11, line 65 through column 12, line 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hayward, Barry, and McKeown. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

38. As per claim 42, Hayward teaches the invention substantially as claimed, see discussion of claim 41, but fails to specifically teach:

--further comprising mapping the static structure elements and the execution constraints to corresponding static structure elements and execution constraints of the generic guideline representation model, to provide a mapping relationship for use by a guideline execution engine.

However, McKeown teaches directly teaches mapping elements (see: McKeown, column 2, lines 37-41), and Barry also teaches rules that incorporate specific elements from knowledge bases into customized treatments and corresponding advisory information (Fig. 2)(see: Barry, column 11, line 65 through column 12, line 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hayward, Barry, and McKeown. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

Conclusion

39. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT SOREY whose telephone number is (571)270-3606. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM (EST).

40. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Gilligan can be reached on (571)272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

41. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. S./
Examiner, Art Unit 3626
13 February 2009

/C. LUKE GILLIGAN/
Supervisory Patent Examiner, Art Unit